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EXAMINER

KASSA, JESSICA M

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,547	<b>Applicant(s)</b> DOSHI ET AL.	
	<b>Examiner</b> JESSICA KASSA	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/10/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/23/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

**Claims 1-38 are pending and are under consideration in the instant office action.**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 1/9/2004. It is noted, however, that applicant has not filed a certified copy of the 0400452.9 application as required by 35 U.S.C. 119(b).

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 5/23/07 is noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites "...comprises one or more pharmaceutical carrier(s) and excipients." It is unclear whether the claim requires one or more pharmaceutical carrier(s) **and** one or more excipient(s) **or** whether the claim merely requires one or more pharmaceutical carrier(s) or excipient(s). For purposes of

Art Unit: 1616

rejections under 35 USC 102 or 103, the examiner interprets the claim to mean one or more pharmaceutical carrier or excipient.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-7 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirakawa et al. (US Patent 5725880).**

4. Hirakawa et al. disclose a pharmaceutical preparation with a **core containing a medicinal active** and a **press-coated layer** provided around the core (abstract). The **press-coat layer** comprises an **enteric polymer** (abstract and column 5, lines 35-38 and 44-52); the examiner notes that there is no mention of an active. Since Hirakawa et al. teaches that the **coating is provided around the core** such that the active is not released in the stomach (abstract and column 3, lines 14-28), the examiner concludes that the press-coated layer constitutes a taste masking layer which encases substantially the whole surface area of the core. Therefore, Hirakawa et al. anticipate instant claims 1, 4, and 7. Since an enteric polymer constitutes an excipient, Hirakawa et al. also anticipates instant claim 14. The enteric polymer used for the press-coating is formed into **granules** (column 5, lines 35-38). The press-coating to form the press-coated layer is carried out, for instance by a **press-coating method** or a **dry coating method** or the like (column 9, line 43-47). Therefore, Hirakawa et al.

Art Unit: 1616

anticipates instant claim 5, 6 and 35. The **press-coat layer may comprise multiple layers** which is formed by press-coating a core with one kind of an enteric polymer and providing a further press-coated layer comprising the same of different kind of an enteric polymer around the layer (column 5, lines 46-52). Therefore, Hirakawa et al. anticipate instant claims 2-3 and 18. In example 1, the plain tablet which forms the **core** of the press-coated tablet is made from **diltiazem hydrochloride mixed with corn starch**; since corn starch constitutes an excipient, Hirakawa et al. anticipate instant claim 13.

5. With respect to the USC 102 rejection above, please note that in product-by-process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference.” MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the “patentability of a product does not depend on its method of production.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants’ method of forming the powder blends or granules as found in instant claim 6 differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

**Claims 1, 4-7, 13-15, 18-19, 21-29, 31-32, 35-36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Dandiker et al. (EPO 0546593, IDS reference).**

6. Dandiker et al. (EP 0543593 A1) teach the formation of a **compression coated tablet** (example 11, page 14, lines 33-34). The examiner notes that there are no active agents in the polymer layer used for the coating (example 11, page 14, lines 23-30). Additionally, the outer polymer layer constitutes a taste masking layer formed on the core by compression. Therefore Dandiker et al. anticipate instant claims 1 and 4. The **outer polymer layer may be evenly distributed over the surface of the preparation**, therefore, the outer polymer layer is expected to cover substantially the whole outer surface of the core; thus Dandiker et al. anticipates instant claim 7. The excipients for the polymer layer were dry mixed and therefore constitute a powder blend which is compressed onto the surface of the core. The **outer polymer layer** may be **applied** using a conventional **tableting press** (page 6, lines 15-17), therefore Dandiker et al anticipates instant claim 5, 6 and 35. Since the core in example 11 comprises 50 mg of sumatriptan succinate, Dandiker et al. also anticipates instant claims 19, 21-27, 36 and 38. Note, the examiner calculates that 50 mg of sumatriptan succinate corresponds to 36 mg of sumatriptan free base. Specifically, the **sumatriptan succinate core** of the tablet comprises **microcrystalline cellulose** (23%), **lactose** (23%), polyvinylpyrrolidone (2%) and sodium stearyl fumarate (2%) (example 11, page 14). Suitable excipients also include **lactose** and **magnesium stearate** (page 4, lines 51 and 54). Therefore, Dandiker et al. anticipate instant claim 13 and 28. The

Art Unit: 1616

sumatriptan succinate was granulated with the excipients used to form the core (example 11, page 14, lines 17-18). Therefore, Dandiker et al. anticipates instant claims 29. The outer layer comprises hydroxypropyl methylcellulose (35%), microcrystalline cellulose (40%), dibasic calcium phosphate (23%), colloidal silicone dioxide (1%) and sodium stearyl fumarate (1%) (example 11, page 4). Therefore, Dandiker et al. anticipate instant claim 15, and 31-32. The core is pressed first followed by compression coating the polymer coating layer on to the core which constitutes a multiple compression method thereby anticipating instant claim 18.

7. With respect to the USC 102 rejection above, please note that in product-by-process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference.” MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the “patentability of a product does not depend on its method of production.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants’ method of forming the powder blends or granules as found in instant claim 6 differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Art Unit: 1616

**Claims 1, 4-6, 13-15, 19, 21-32 rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (WO03/075893 A1, IDS reference).**

8. Lerner et al. teach a pharmaceutical tablet for taste masking (example 5, line 5-13). The outer mantle (coating) is applied by compression (page 37, lines 19-22). The outer coating comprises **sucrose, microcrystalline cellulose, and magnesium searate** (page 37, lines 16-18). The examiner notes that the outer coating does not contain any active ingredients, therefore, Lerner et al. anticipates instant claims 1 and 4-6. The examiner calculates the amount of sucrose in the outer coating is 349 mg, the amount of microcrystalline cellulose is 18.5 mg and the amount of magnesium stearate is 3.7 mg. Therefore, Lerner et al. anticipate instant claim 14-15, and 31-32. The core comprises **sumatriptan succinate, microcrystalline cellulose, lactose, croscarmellose sodium and magnesium searate** (example 5, lines 5-13). Therefore, Lerner et al. anticipate instant claims 13, 21-25 and 28-29. The amount of sumatriptan succinate is equivalent to 25 mg of sumatriptan free base (page 37, lines 12-13) thus anticipating instant claims 19 and 26-27. The examiner calculates that the amount of microcrystalline cellulose in the core is 18 mg; the amount of lactose in the core is 9 mg the amount of croscarmellose sodium is 5 mg and the amount of magnesium stearate is 1 mg. Therefore, Lerner et al. anticipates instant claim 30.

9. With respect to the USC 102 rejection above, please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102 is proper



Art Unit: 1616

because the “patentability of a product does not depend on its method of production.”

*In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants’ method of forming the powder blends or granules as found in instant claim 6 differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

**Claims 1, 4-6, 13, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ventouras (US Patent 4784858).**

10. Ventouras discloses a controlled release tablet with at least one pharmacuetically acitive agent and a polymer coating. The polymer coating is expected to be taste masking, therefore, Ventouras anticipates instant claim 1, 4-7 and 18. In example 1, the core comprises the actives proxyphylline, diprophylline, and anhydrous theophylline. Therefore, Ventouras anticipates instant claim 20. The actives are then granulated with polyvinylpyrrolidone which constitutes an excipient, therefore, Ventouras anticipates instant claim 13.

11. With respect to the USC 102 rejection above, please note that in product-by-process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an

Art Unit: 1616

unobvious difference.” MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the “patentability of a product does not depend on its method of production.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants’ forming the taste masking layer found in instant claims 1, 4-6 and 18 differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1616

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 16 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (EP0546593 A1, IDS reference) as applied to claims 1, 4-7, 13-15, 18-19, 21-29, 31-32, 35-36 and 38 above in view of Lerner et al. (WO 03/75893, IDS reference) as applied to claims 1, 4-6, 13-15, 19, 21-32 above.**

***Applicants' claims***

12. Applicants claim a taste masking pharmaceutical composition and methods of use and preparation thereof.

***Determination of the Scope and Content of the Prior Art***

***(MPEP 2141.01)***

13. The reference of Dandiker et al. is discussed in detail above and that discussion is hereby incorporated by reference. Furthermore, Lerner et al. teach the annular body (i.e. the compression coating) may be made using known diluents (fillers), disintegrants, binder, lubricants and the like (page 7, lines 28-29). Including, for example microcrystalline cellulose, lactose, etc.

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims***

***(MPEP 2141.02)***

14. Dandiker et al. and Lerner et al. do not specifically teach the exact amounts and combinations of excipients. ***Finding of Prima Facie Obviousness Rational and Motivation***

**(MPEP 2142-2143)**

15. It would have been obvious to the skilled artisan at the time the present invention was made to select suitable fillers, disintegrants and lubricants and to optimize there concentrations and thus produce the instantly claimed invention since Lerner et al. teach the coating can be made with any suitable excipients. Furthermore the examiner notes that modifying the coating composition of Lerner et al. by substituting lactose for sucrose and adding some croscarmellose sodium to coating would result in the instantly claimed invention assuming a slight adjustment in the amounts of the excipients to account for the added croscarmellose sodium. Furthermore, the examiner notes that the croscarmellose was already used in the sumatriptan tablet of Lerner et al. as disintegrant in the core. The skilled artisan would be motivated to optimize the coating composition to ensure appropriate degradation rate for the coating and consequentially suitable release rates for the sumatriptan. The skilled artisan would have a reasonable expectation of success since the coating composition of Lerner et al. is substantially similar to the instantly claimed coating composition.

16. In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

17. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

Art Unit: 1616

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Claims 20, 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (EP0546593 A1, IDS reference) as applied to claims 1, 4-7, 13-15, 18-19, 21-29, 31-32, 35-36 and 38 above in view of Lerner et al. (WO 03/75893, IDS reference) as applied to claims 1, 4-6, 13-15, 19, 21-32 above further in view of Plachetka (US Patent 6060499).**

***Applicants' claims***

18. Applicants claim a taste masking pharmaceutical composition and methods of use and preparation thereof.

***Determination of the Scope and Content of the Prior Art***

***(MPEP 2141.01)***

19. The reference of Dandiker et al. is discussed in detail above and that discussion is hereby incorporated by reference.

20. Plachetka teaches that a **combination therapy** of a 5-HT agonist, including drugs structurally similar to 5-HT agonists like **sumatriptan** or like members of the ergot family of compounds, **combined with a long acting nonsteroidal anti-inflammatory drug** (NSAID) substantially reduces or eliminates the relapse phenomenon in a significant portion of migraineurs that otherwise experience relapse and that the combination of the two agents results in an **enhanced therapeutic effect** allowing for greater and/or longer lasting efficacy and/or lower doses than can be obtained with the conventional doses of either individual agent (column 4, lines 50-60).

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims***  
***(MPEP 2141.02)***

21. Dandiker et al. and Lerner et al. do not specifically teach the incorporation of a second active. This deficiency is cured by Plachetka (US Patent 6060499).

***Finding of Prima Facie Obviousness Rational and Motivation***  
***(MPEP 2142-2143)***

22. It would have been obvious to the skilled artisan at the time the present invention was made to include a second active agent in the sumatriptan core of either Dandiker et al. or Lerner et al. and thus produce the instantly claimed invention since Plachetka teaches that the combination of sumatriptan with nonsteroidal anti-inflammatory drugs produces an enhanced therapeutic effect. The skilled artisan would be motivated to include the second active to provide greater and/or longer lasting efficacy and/or lower doses as taught by Plachetka. The skilled artisan would have a reasonable expectation of success since incorporating a second active into a pharmaceutical composition is within the purview of the skilled artisan.

23. It would have been obvious to the skilled artisan at the time the present invention was made to administer the sumatriptan and/or sumatriptan/nonsteroidal anti-inflammatory compositions to treat migranes since Plachetka teaches that sumatriptan and/or sumatriptan/ nonsteroidal anti-inflammatory compositions are used to treat individuals suffering from migranes. The skilled artisan would be motivated to treat humans suffering from migranes to alleviate the headaches. The skilled artisan would

Art Unit: 1616

have a reasonable expectation of success since the use of tablets for pain relief is well known.

24. In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

25. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Claims 8-12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (EP0546593 A1, IDS reference) as applied to claims 1, 4-7, 13-15, 18-19, 21-29, 31-32, 35-36 above, and further in view of Waterman (US Patent Application Publication 2003/0143272, IDS reference).**

***Applicants' claims***

26. Applicants claim a taste masking pharmaceutical composition and methods of use and preparation thereof.

***Determination of the Scope and Content of the Prior Art***

***(MPEP 2141.01)***

27. The reference of Dandiker et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Art Unit: 1616

28. Waterman teaches compressible coatings with several advantages over conventional cellulose-based coatings. For example, the inventive compressible coating can collapse after the bulk of the drug is delivered into the GI tract. An additional advantage is the ability to imprint (emboss) a form of identification onto the final tablet surface. This identification can be used as an anti-counterfeit method or for brand identification (paragraph 66). An additional film coating may be added to mask the taste of the drug, provide for easier swallowing, impart chemical or physical stability, provide an enteric coating or allow for identification (e.g., by providing a specific color, or printed logo or trademark).

***Ascertainment of the Difference Between Scope of the Prior Art and the Claims***

***(MPEP 2141.02)***

29. Dandiker et al. do not specifically teach the outer surface layer having a surface profile such as a printed indicia or intaglio. Dandiker et al. also do not teach an additional film coating. These deficiencies are cured by Waterman.

***Finding of Prima Facie Obviousness Rational and Motivation***

***(MPEP 2142-2143)***

30. It would have been obvious to the skilled artisan at the time the present invention was made to form a surface profile on the surface of the composition of Dandiker et al. and thus produce the instantly claimed invention since Waterman teaches that one advantage of such surface coatings is the capacity to form such surface profiles. The skilled artisan would be motivated to form the surface profile in order to better identify the composition and protect against counterfeiting. Since intaglio which are formed by



Art Unit: 1616

engraving or etching and printed indicia are discriminating marks or signs, the surface markings such as a trademark taught by Waterman constitute intaglio and printed indicia. The skilled artisan would have a reasonable expectation of success since Waterman teaches the formation of such surface profiles on compression coatings and the composition of Dandiker et al. is compression coated.

31. It would also have been obvious to the skilled artisan at the time the present invention was made to add an additional film coating and thus produce the instantly claimed invention since Waterman teaches the use of film coatings on compression coated tablet. The skilled artisan would have been motivated to add the film coating in order to improve taste masking, ease of swallowing, etc. The skilled artisan would have a reasonable expectation of success since Waterman teaches that the film coating may be carrier out by processes well known to those skilled in the art (paragraph 80).

32. In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

33. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Art Unit: 1616

**Conclusion**

Claims 1-38 are pending and are under consideration in the instant office action.  
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JESSICA KASSA whose telephone number is (571)270-1342. The examiner can normally be reached on 5:30am- 2pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica M. Kassa  
Patent Examiner  
AU 1616

/Ernst V Arnold/  
Primary Examiner, Art Unit 1616